

*A²
c/d*
21. (Amended) A kit according to claim 17, wherein

 said ultrashort pulse laser is a laser selected from a group consisting of a femtosecond laser, a picosecond laser and an attosecond laser.

22. (Amended) A kit according to claim 17, wherein

 said second laser is an excimer laser.

REMARKS

In the April 8, 2002 Office Action, of pending claims 1-25, claims 17-22 are rejected under 35 U.S.C. §112, second paragraph and 35 U.S.C. §103(a) and claims 1-16 and 23-25 are rejected under nonstatutory double patenting.

By this Amendment, claims 17-22 are amended, leaving claims 1-25 pending with claims 1, 13, 17 and 23 being independent.

Reconsideration and allowance of the above-identified application is respectfully requested.

Rejections Under 35 U.S.C. §112, second paragraph

Claims 17-22 are rejected under 35 U.S.C. §112, second paragraph as being indefinite. Specifically, the Action alleges that each of these claims appears to be a collection of elements intended to be used to perform a process that is more accurately a kit.

As noted above, claims 17-22 have been amended to include the word "kit", and therefore it is believed that they now overcome the §112, second paragraph rejection. Applicant further notes that this amendment is not made to limit the scope of the claims and believes that the word "system", as used in the claims of the application, does not in itself render the above claims indefinite. However, to expedite prosecution, Applicant has amended the above claims, as requested by the Examiner.

Claims 18 and 20 are also rejected since there is allegedly no further structure recited by the description of intended use. Applicant submits that as noted above, each of these claims is amended to overcome this rejection.

Rejections Under 35 U.S.C. §103(a)

Claims 17-22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over WO 87/07165 to Sklar et al. in view of over U.S. Patent No. 5,318,047 to Davenport et al.

Applicant respectfully traverses this rejection.

The combination of the Sklar application and the Davenport et al. patent does not disclose, teach or suggest all the elements of independent claim 17. Specifically, the combination does not disclose, teach or suggest a laser that is adapted to separate the cornea offset from the main optical axis into first and second internal surfaces to form a flap. Furthermore, the combination does not disclose, teach or suggest inserting an implant under a corneal flap, but rather the Davenport et al. patent teaches tunneling an implant through the cornea, which can stretch the cornea and thereby cause the refractive properties of the cornea to be altered.

The Action states that the Sklar et al. application discloses all the elements of claims 17-22, except the ocular implant. For the use of the implant, the Action relies on the Davenport et al. patent, stating that it would have been obvious to one of ordinary skill in the art to modify the Sklar et al. invention, since the corneal implant could be used on patients, which require an optical correction so great that it cannot be provided by laser surgery. Clearly this combination does not disclose, teach or suggest all the elements of independent claim 17.

Claim 17 recites, among other things, a kit for corrective surgery for a cornea, including an ultrashort pulse laser adapted to separate the internal area of the cornea offset from the main optical axis and an ocular implant adapted to be inserted in between the first and second internal surfaces of the corneal flap. A second laser is adapted to ablate a portion of an external surface of the cornea after said ocular implant is inserted in-between the first and second internal surfaces of the corneal flap. By forming a flap offset from the main optical axis, the primary visual portion of the cornea does not have any separation thereon and therefore is there is little or no likelihood of scaring along the primary visual axis.

First, the Sklar et al. application clearly does not disclose, teach or suggest any type of corneal implant. The Sklar et al. invention is primarily for making cuts in tissue for laser surgery, and not for implantation of intracorneal inlays. Second, the Sklar application does not disclose, teach or suggest an ultrashort pulse laser adapted to separate the internal area of the cornea offset from the main optical axis. In fact, there is no specific disclosure that the Sklar et al. device could be used or is even capable of forming a flap, as recited in independent claim 17.

The Sklar et al. laser is primarily used for making cuts in tissue for ophthalmic procedures. These cuts are generally wounds made from the exterior of the eye to a predetermined level of the stroma, as noted on page 3, lines 1-2. Furthermore, as noted on page 48, lines 5-7 of the Sklar et al. disclosure, all laser bursts were kept within the stroma of the cornea or superficial to the suture in the case of muscle tendon sheath. There is no disclosure, in the Sklar et al. application, of a laser adapted to separate the internal area of the cornea in the surface of the cornea, and more precisely there is no disclosure of a laser adapted form a flap offset from the main optical axis.

The Davenport et al. patent teaches implanting a corneal ring 47 in the stromal layer of the cornea. As described in col. 4, lines 64-68 and col. 5, lines 1-4, an incision is placed in the corneal stroma and a channel blade is inserted at the depth of the incision and a circular channel is cut in the stroma. The ring is then inserted and the ends of the ring are fastened together.

This type of procedure requires tunneling through the corneal stroma for implantation of the corneal ring. The ring then generally stretches the cornea to reshape the surface of the cornea, thereby changing the cornea's refractive properties.

There is however, no disclosure, teaching or suggestion of either (1) a laser adapted form a flap offset from the main optical axis; or (2) an ocular implant adapted to be inserted in between the first and second internal surfaces of the corneal flap. By forming a flap and inserting the ocular implant under the flap, as recited in claim 17, there is no stretching of the cornea and therefore, less likelihood that the refractive properties of the cornea will be altered due to the tension imposed thereon, rather than mere change in curvature.

The combination of the Sklar et al. application and the Davenport et al. patent fails to disclose every element of the claimed invention, and therefore does establish a *prima facia* case of obviousness. The prior art references, when combined must teach or suggest all the claim limitations to establish a *prima facia case* of obviousness. MPEP §2142. Clearly there is no teaching or suggestion of the laser being adapted to separate the cornea offset from the main optical axis into first and second internal surfaces to form a flap. Furthermore, there is no teaching or suggestion of an ocular implant adapted to be inserted in between the first and second internal surfaces of the corneal flap. At best, the combination of references would teach firing an excimer laser at the external surface of the cornea and inserting a ring under the surface of the cornea by forming a tunnel in the cornea.

Applicant submits that since the combination of the Sklar et al. application and the Davenport et al. patent clearly does not disclose, teach or suggest all the elements of independent claim 17, claim 17 and its dependent claims 18-22 are allowable.

Double Patenting Rejection

Claims 1-16 and 23-25 are rejected under the judicially created doctrine of obviousness type double patenting over claims 1-5 of U.S. Patent No. 6,217,571 to Peyman in view of U.S. Patent 4,907,586 to Bille et al. The Peyman patent is cited as disclosing all the elements of these claims, except the use of an ultrashort pulse laser. In support of the rejection, the Action states that it would have been obvious to create a stromal pocket using a laser as taught in Bille et al., since the laser leaves a smoother surface.

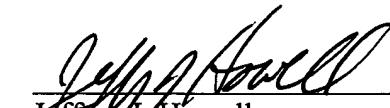
As suggested by the Examiner, a Terminal Disclaimer is filed herewith to overcome this rejection.

* * *

In view of the above, it is believed that the above-identified application is in condition for allowance, and notice to that effect is respectfully requested. Should the Examiner have any questions, the Examiner is encouraged to contact the undersigned at the local telephone number indicated below.

Attached hereto is a marked-up version of the changes made to the claims by the current amendments. The attached page is captioned "Version With Markings To Show Changes Made".

Respectfully submitted,



Jeffrey J. Howell
Reg. No. 46,402
Attorney for Applicant

Roylance, Abrams, Berdo & Goodman, L.L.P.
1300 19th Street, N.W., Suite 600
Washington, D.C. 20036-2680
(202) 659-9076

Dated: August 8, 2002

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please amend claims 17-22 as follows:

17. (Amended) A [system] kit for corrective surgery for a cornea of an eye having a main optical axis, comprising:

an ultrashort pulse laser adapted to separate the internal area of the cornea offset from the main optical axis into first and second internal surfaces to form a corneal flap;

an ocular implant adapted to be inserted in between the first and second internal surfaces of the corneal flap; and

a second laser adapted to ablate a portion of an external surface of the cornea after said ocular implant is inserted in-between the first and second internal surfaces of the corneal flap.

18. (Amended) A [system] kit according to claim 17, wherein

said ultrashort pulse laser is a laser selected from a group consisting of a femtosecond laser, a picosecond laser and an attosecond laser and is adapted to form said flap, so that a portion of said flap remains attached to the cornea by an area located at said main optical axis, said first internal surface facing in a posterior direction of said cornea and said second internal surface facing in an anterior direction of said cornea.

19. (Amended) A [system] kit according to claim 18, wherein
said ocular implant is a substantially ring-shaped ocular implant and is adapted to be
inserted so that said ocular implant at least partially encircles said portion of the cornea that
remains attached to said cornea by an area located at said main optical axis.

20. (Amended) A [system] kit according to claim 19, wherein
said second laser is an excimer laser and is adapted to ablate the external surface of the
cornea at said portion of said corneal flap that remains attached to said cornea by the area
located at said main optical axis.

21. (Amended) A [system] kit according to claim 17, wherein
said ultrashort pulse laser is a laser selected from a group consisting of a femtosecond
laser, a picosecond laser and an attosecond laser.

22. (Amended) A [system] kit according to claim 17, wherein
said second laser is an excimer laser.